IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. WALL CARDIOVASCULAR TECHNOLOGIES, LLC, Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively, "Boston Scientific"), for their Complaint against Defendant Wall Cardiovascular Technologies, LLC, hereby allege as follows.

THE PARTIES

1. Plaintiff Boston Scientific Corporation is a Delaware corporation having a principal place of business at One Boston Scientific Place, Natick, Massachusetts 01760.

2. Plaintiff Boston Scientific Scimed, Inc. is a Minnesota corporation having a principal place of business at One Scimed Place, Maple Grove, Minnesota 55311.

3. Upon information and belief, defendant Wall Cardiovascular Technologies, LLC ("Wall") purports to be a Texas limited liability company having a principal place of business in Marshall, Texas. Upon further information and belief, Wall does not manufacture or sell any

products, devices or services and has as its principal business model asserting and threatening to assert patents in litigation for money.

NATURE OF THE ACTION

4. This is a civil action for a declaratory judgment of noninfringement, invalidity and unenforceability of United States Patent No. 6,974,475 ("the '475 patent") due to inequitable conduct and prosecution history laches.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and 28 U.S.C. §§ 1331 and 1338(a). As demonstrated by, *inter alia*, Wall's filing of patent infringement claims based on the '475 patent against Abbott Laboratories and Abbott Cardiovascular Systems, Inc. (collectively, "Abbott") in connection with Abbot's drug-eluting XIENCE® stents, Case No. 2:08-cv-289 (E.D. Tex.), an actual and justiciable controversy exists between Boston Scientific and Wall regarding the noninfringement, invalidity and unenforceability of the '475 patent with respect to Boston Scientific's PROMUS® brand drug-eluting stents.

6. Wall is subject to personal jurisdiction in this Court as evidenced by, *inter alia*, its sending of letters to Delaware corporations alleging infringement of the '475 patent, its negotiating with Delaware corporations regarding potential license terms for the '475 patent, and its filing of complaints against Delaware corporations alleging infringement of the '475 patent.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b).

RELEVANT FACTS

8. Upon information and belief, Abbott manufactures, sells and distributes drug-eluting stents under the trade name XIENCE®.

9. Pursuant to a Supply Agreement between Boston Scientific and Abbott, Abbott has provided and will provide Boston Scientific with XIENCE® stents, which Boston Scientific sells and will sell under the PROMUS® brand. Pursuant to the Supply Agreement, Boston Scientific also has a license to directly manufacture and sell PROMUS® stents if it so chooses. The XIENCE® stent and PROMUS® stent share the same structure and mechanism of action.

10. On July 25, 2008, Wall filed a complaint against Abbott in the United States District Court for the Eastern District of Texas, alleging that Wall holds all rights and interest in the '475 patent and that Abbott's XIENCE® stents infringe the '475 patent. In that complaint, Wall alleged that it received all rights and interest in the '475 patent from Dr. W. Henry Wall via W.H. Wall Family Holdings GP, LLC and W.H. Wall Family Holdings, LLLP.

11. On November 16, 2007, Wall filed a complaint against Boston Scientific in the United States District for the Eastern District of Texas, alleging that Wall holds all rights and interest in the '475 patent and that Boston Scientific's drug-eluting TAXUS EXPRESS® stents infringe the '475 patent.

CLAIM I: DECLARATORY JUDGMENT OF NONINFRINGEMENT

12. Boston Scientific hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1-11 as though set forth herein in their entirety.

13. Boston Scientific's PROMUS® stents do not infringe any claim of the '475 patent, either directly, indirectly, literally or under the doctrine of equivalents.

14. Wall has alleged that Abbott's XIENCE® stents — *i.e.*, the stents Boston Scientific sells as the PROMUS® stents and has a license to manufacture — infringe the '475 patent.

15. Therefore, there exists an actual and justiciable controversy between Boston Scientific and Wall with respect to the noninfringement of the '475 patent by the PROMUS® stents.

16. A judicial declaration of noninfringement of the '475 patent by the PROMUS® stents is necessary and appropriate to resolve this controversy.

CLAIM II: DECLARATORY JUDGMENT OF INVALIDITY

17. Boston Scientific hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1-16 as though set forth herein in their entirety.

18. Every claim of the '475 patent is invalid for failure to comply with one or more of the conditions for patentability specified in part II of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102 and/or 103.

19. Every claim of the '475 patent is additionally invalid for failure to comply with one or more of the requirements of 35 U.S.C. § 112.

20. On information and belief, Wall alleges that every claim of the '475 patent is valid.

21. Therefore, there exists an actual and justiciable controversy between Boston Scientific and Wall with respect to the invalidity of the '475 patent.

22. A judicial declaration of invalidity of the '475 patent is necessary and appropriate to resolve this controversy.

CLAIM III: DECLARATORY JUDGMENT OF UNENFORCEABILITY DUE TO INEQUITABLE CONDUCT

23. Boston Scientific hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1-22 as though set forth herein in their entirety.

24. The '475 patent is completely and permanently unenforceable due to inequitable conduct before the United States Patent And Trademark Office ("USPTO"). Numerous examples of this inequitable conduct are discussed below and Boston Scientific believes that additional examples are likely to have evidentiary support after a reasonable opportunity for further investigation and discovery.

25. The '475 patent issued from U.S. Patent Application Serial No. 07/129,834 ("the '834 application"). The named inventor on the '834 application also filed U.S. Patent Application No. 10/293,122 ("the '122 application"). The '122 application is titled "Method Of Implanting A Sleeve In A Lumen" and was filed on November 13, 2002. The '122 application purports to be a divisional of the '834 application. As a result, the '122 application contains the same specification and drawings as '834 application.

26. As an example of the inequitable conduct before the USPTO that renders the '475 patent unenforceable, as part of the filing and prosecution of the '834 application, which issued as the '475 patent, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the material reference U.S. Patent No. 4,733,665 ("the

'665 patent") to the USPTO. Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the '665 patent with the intent to deceive the USPTO into granting a patent on the '834 application.

27. Upon information and belief, a reasonable Patent Examiner would have considered the '665 patent highly material to the patentability of the claims of the '834 application. For example, the prior art '665 patent discloses a stent made from a mesh of wire material and having a biologically compatible coating.

28. Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO knew of the '665 patent and its materiality during prosecution of the '834 application and still failed to cite it to the USPTO. For example, in connection with prosecution of the '122 application, the '665 patent was disclosed in an Information Disclosure Citation. Moreover, on December 17, 2003, in connection with prosecution of the '122 application, the Patent Examiner listed the '665 patent as a cited reference in an office action. On January 21, 2004, while prosecuting the '122 application, the applicant filed a response to the December 17, 2003 office action.

29. Despite the overlap of subject matter in the '834 and '122 applications, and despite having knowledge that the '665 patent was relevant to the prosecution of the '834 application, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO still did not disclose the '665 patent to the USPTO during prosecution of the '834 application. This failure to disclose the highly material '665 patent was motivated by, and accomplished with, the intent to deceive the USPTO into granting the patent that issued as the '475 patent asserted in this action.

30. As another example of the inequitable conduct before the USPTO that renders the '475 patent unenforceable, as part of the filing and prosecution of the '834 application, which issued as the '475 patent, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the material reference U.S. Patent No. 5,059,211 ("the '211 patent"). Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the '211 patent with the intent to deceive the USPTO into granting a patent on the '834 application.

31. Upon information and belief, a reasonable Patent Examiner would have considered the '211 patent highly material to the patentability of the claims of the '834 application. For example, the prior art '211 patent discloses a stent with walls having openings to facilitate tissue ingrowth and encapsulation of the stent.

32. Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO knew of the '211 patent and its materiality during prosecution of the '834 application and still failed to cite it to the USPTO. For example, during prosecution of the '122 application, the '211 patent was disclosed in an Information Disclosure Citation.

33. Despite the overlap of subject matter in the '834 and '122 applications, and despite having knowledge that the '211 patent was relevant to the prosecution of the '834 application, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO still did not disclose the '211 patent to the USPTO during prosecution of the '834 application. This failure to disclose the highly material '211 patent was motivated by, and accomplished with, the intent to deceive the USPTO into granting the patent that issued as the '475 patent asserted in this action.

34. As another example of the inequitable conduct before the USPTO that renders the '475 patent unenforceable, as part of the filing and prosecution of the '834 application, which issued as the '475 patent, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the material reference U.S. Patent No. 4,776,337 ("the '337 patent"). Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the '337 patent with the intent to deceive the USPTO into granting a patent on the '834 application.

35. Upon information and belief, a reasonable Patent Examiner would have considered the '337 patent highly material to the patentability of the claims of the '834 application. For example, the prior art '337 patent discloses a stent made from a mesh of wire material and having a biologically compatible coating.

36. Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO knew of the '337 patent and its materiality during prosecution of the '834 application and still failed to cite it to the USPTO. For example, in connection with prosecution of the '122 application, patents issued to Palmaz, including the '665 patent and U.S. Patent No. 4,739,762 ("the '762 patent"), and a journal article authored by Palmaz were disclosed in an Information Disclosure Citation. Moreover, in connection with prosecution of the '834 patent, monographs authored by Palmaz and a district court opinion relating to the '762 patent were disclosed in an Information Disclosure Citation.

37. Upon information and belief, as demonstrated by the references relating to the Palmaz stent that were made of record during the prosecution of the '834 and '122 applications, applicant was also aware of the '337 patent. Despite having knowledge that the '337 patent was relevant to the prosecution of the '834 application, the named inventor and/or others with a duty

of candor and good faith in dealing with the USPTO still did not disclose the '337 patent to the USPTO during prosecution of the '834 application. This failure to disclose the highly material '337 patent was motivated by, and accomplished with, the intent to deceive the USPTO into granting the patent that issued as the '475 patent asserted in this action.

38. As another example of the inequitable conduct before the USPTO that renders the '475 patent unenforceable, as part of the filing and prosecution of the '834 application, which issued as the '475 patent, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose a material reference, the August 1987 Wall Street Journal article regarding the Palmaz stent ("the Wall Street Journal article"). Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO failed to disclose the Wall Street Journal article with the intent to deceive the USPTO into granting a patent on the '834 application.

39. Upon information and belief, a reasonable Patent Examiner would have considered the Wall Street Journal article highly material to the patentability of the claims of the '834 application, including, but not limited to, claims that were originally presented in the '122 application and later added to the '834 application. For example, the Wall Street Journal article discloses a method of using a stent made from a mesh tube to hold open a body vessel to a desired diameter.

40. Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO knew of the Wall Street Journal article and its materiality during prosecution of the '834 application and still failed to cite it to the USPTO. For example, upon information and belief, the applicant provided the Wall Street Journal article to C.R. Bard, Inc. on August 21, 1987, several months prior to filing the '834 application. Despite

having knowledge that the Wall Street Journal article was relevant to the prosecution of the '834 application, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO still did not disclose the article to the USPTO during prosecution of the '834 application. This failure to disclose the highly material Wall Street Journal article was motivated by, and accomplished with, the intent to deceive the USPTO into granting the patent that issued as the '475 patent asserted in this action.

41. As another example of the inequitable conduct before the USPTO that renders the '475 patent unenforceable, as part of the filing and prosecution of the '834 application, which issued as the '475 patent, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO made materially false statements with the intent to deceive the USPTO into granting a patent on that application.

42. On January 7, 1993, Interference No. 102,994 was declared between the '834 application and U.S. Patent No. 4,740,207 to Kreamer ("the '207 patent"). This interference was provoked by the applicant in a September 20, 1988 response to an office action. On June 28, 1995, the Board Of Patent Appeals And Interferences ("the BPAI") ruled against applicant. On February 19, 1997, the U.S. Court Of Appeals For The Federal Circuit dismissed the applicant's appeal of this ruling. This dismissal affirmed the rejection of some, but not all, of the pending claims of the '834 application.

43. On August 20, 2004, the USPTO issued an office action resuming *ex parte* prosecution of the claims of the '834 application. On September 20, 2004, the '834 application was deemed abandoned by the Patent Examiner due to the applicant's failure to respond to the August 20, 2004 office action. On February 14, 2005, the applicant filed a Petition For Revival and a Request To Withdraw And Re-Mail Office Action Dated August 20, 2004. In its Request

To Withdraw And Re-Mail Office Action Dated August 20, 2004, the applicant stated that: "The Office Action that was issued by the Office was the first Office Action issued in this file for several years. Applicant and his attorney were not aware of a likelihood that an Office Action would be issued in this application file and did not anticipate that an Office Action would be issued."

44. Upon information and belief, contrary to this representation to the USPTO, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO were aware that the '834 application contained claims that were still active after the February 19, 1997 Federal Circuit decision in connection with Interference No. 102,994. For example, during prosecution of U.S. Patent Application Serial No. 08/667,604 ("the '604 application"), the applicant filed a terminal disclaimer stating that "[t]he applicant disclaims the terminal portion of any patent that may issue to the above captioned U.S. patent application that extends beyond the expiration of any patent that may issue to U.S. patent application No. 07/129,834." It is apparent from at least this statement that the applicant knew as of August 12, 1999 that certain claims of the '834 application were still pending.

45. Moreover, in a March 17, 2005 communication with the USPTO in connection with the '834 application, the applicant cited MPEP § 1216.01, noting that for "an application received back from the Court of Appeals of the Federal Circuit, when some claims have been allowed," "the proceedings are considered terminated only as to any claims which still stand rejected." Moreover, upon information and belief, between February 19, 1997 and February 14, 2005, the applicant actively prosecuted continuations, continuations-in-part and/or divisionals of the '834 application, including the '122 application and U.S. Patent Application Serial No. 08/578,504 and the '604 application, none of which would have been possible if there were not

still claims pending in the '834 application. Furthermore, on December 7, 1993, Dr. William Henry Wall, the sole named inventor on the '834 application, testified in a deposition in connection with Interference No. 102,994 that he was "very familiar with the patent process."

46. Upon information and belief, a reasonable Patent Examiner would have considered the fact that the applicant was aware that the '834 application contained claims that were still active after the February 19, 1997 Federal Circuit decision in connection with Interference No. 102,994 to be material to the patentability of the claims of the '834 application. For example, a reasonable Patent Examiner would have considered this awareness material in deciding whether to grant the applicant's February 14, 2005 Petition For Revival and Request To Withdraw And Re-Mail Office Action Dated August 20, 2004.

47. Upon information and belief, the named inventor and/or others with a duty of candor and good faith in dealing with the USPTO knew that the '834 application contained claims that were still active after the February 19, 1997 Federal Circuit decision in connection with Interference No. 102,994, knew that this fact was material and intentionally misled the USPTO into believing that the applicant had no such awareness in order to deceive the USPTO into granting a patent on that application.

48. On information and belief, Wall alleges that the '475 patent is enforceable.

49. Therefore, there exists an actual and justiciable controversy between Boston Scientific and Wall with respect to the unenforceability of the '475 patent due to inequitable conduct.

50. A judicial declaration of unenforceability of the '475 patent due to inequitable conduct is necessary and appropriate to resolve this controversy.

CLAIM IV: DECLARATORY JUDGMENT OF UNENFORCEABILITY DUE TO PROSECUTION HISTORY LACHES

51. Boston Scientific hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1-50 as though set forth herein in their entirety.

52. The '475 patent is completely and permanently unenforceable due to prosecution history laches.

53. The '834 application was filed on December 8, 1987. The '834 application issued as the '475 patent over 18 years later, on December 13, 2005. Between December 8, 1987 and December 13, 2005, there were numerous developments in the stent field, including the development of the PROMUS® stents. Upon information and belief, representatives of Wall and/or its corporate predecessors and/or Dr. William Henry Wall were aware of these developments throughout the prosecution of the '834 application.

54. On January 7, 1993, Interference No. 102,994 was declared between the '834 application and the '207 patent. This interference was provoked by the applicant in a September 20, 1988 office action response. On June 28, 1995, the BPAI ruled against the applicant. On February 19, 1997, the U.S. Court Of Appeals For The Federal Circuit dismissed applicant's appeal of this ruling. On August 20, 2004, the USPTO issued an office action resuming *ex parte* prosecution of the claims that were not subject to the interference. The applicant did not respond to this office action until February 14, 2005.

55. Pursuant to MPEP §§ 2308 and 203.08, the burden was on the applicant to initiate *ex parte* prosecution after the Federal Circuit's February 19, 1997 dismissal of the applicant's appeal.

56. Between February 19, 1997 and February 14, 2005, the applicant could have continued prosecuting the claims that were not subject to Interference No. 102,994, but delayed doing so. Upon information and belief, the applicant was aware that it could have continued prosecuting these claims and delayed doing so unreasonably and with the bad-faith intent to keep the application pending and reap the benefits of that status, including the ability to use the application as a priority basis for other applications and to claim a longer term on any resulting patent, without any scrutiny by the USPTO.

57. For example, in a March 17, 2005 communication with the USPTO in connection with the '834 application, the applicant cited MPEP § 1216.01 in noting that, for "an application received back from the Court of Appeals of the Federal Circuit, when some claims have been allowed," "the proceedings are considered terminated only as to any claims which still stand rejected."

58. Moreover, upon information and belief, between February 19, 1997 and February 14, 2005, the applicant actively prosecuted continuations, continuations-in-part and/or divisionals of the '834 application, including the '122 application and U.S. Patent Application Serial Nos. 08/578,504 and 08/667,604.

59. Despite having this knowledge, between February 19, 1997 and February 14, 2005, no action was taken by the applicant with respect to the continued prosecution of the '834 application. For example, the applicant did not file any status inquiries, despite having filed such status inquiries in connection with the '834 application on at least four prior occasions: May 12, 1989; April 23, 1990; November 14, 1990; and July 11, 1991.

60. Moreover, on January 25, 2005, the claims from the co-pending '122 application were allowed by the USPTO. Rather than permit the claims from the '122 application to issue,

however, the applicant further protracted prosecution of these claims by requesting that they be combined with the still pending claims of the '834 application. By combining the claims of the '122 application with the claims of the '834 application, the applicant confirmed its awareness that the '834 application was still a "live" file in the USPTO and effectively and improperly extended the patent term of the claims that previously were part of the '122 application. For example, any claims of a patent issuing from the '122 application would have expired on December 8, 2007.

61. The unreasonable and bad-faith delay during prosecution of the '475 patent resulted in material prejudice and injury to BSC. For example, BSC continued to invest significant time and money in testing, researching and developing existing and new and improved stent products during this delay.

62. On information and belief, Wall alleges that the '475 patent is enforceable.

63. Therefore, there exists an actual and justiciable controversy between Boston Scientific and Wall with respect to the unenforceability of the '475 patent due to prosecution history laches.

64. A judicial declaration of unenforceability of the '475 patent due to prosecution history laches is necessary and appropriate to resolve this controversy.

PRAYER FOR RELIEF

WHEREFORE, Boston Scientific prays for entry of judgment:

A. Declaring that Boston Scientific's PROMUS® stents do not infringe the '475 patent;

B. Declaring that the '475 patent is invalid;

C. Declaring that the '475 patent is unenforceable due to inequitable conduct;

D. Declaring that the '475 patent is unenforceable due to prosecution history laches;

E. Enjoining Wall, its officers, agents, servants, employees and attorneys, and all persons in active concert or participation with any of them who receive actual notice of the injunction by personal service or otherwise from directly or indirectly charging infringement, or instituting any further action for infringement of the '475 patent, against Boston Scientific and/or any of its affiliates, customers, licensees or potential customers or licensees with respect to the PROMUS® stent;

F. Declaring this case to be exceptional within the meaning of 35 U.S.C. § 285 and awarding Boston Scientific the attorney fees, costs, and expenses that it incurs in connection with this action; and

G. Awarding Boston Scientific such other and further relief as the Court deems just and proper.

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Dated: August 6, 2008

TAB 1

US006974475B1

(12) **United States Patent**
Wall

(10) **Patent No.: US 6,974,475 B1**
(45) **Date of Patent: Dec. 13, 2005**

(54) **ANGIOPLASTY STENT**

(76) Inventor: **W. Henry Wall**, 5139 Jimmy Carter Blvd., Ste 201, Norcross, GA (US) 30071

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 903 days.

(21) Appl. No.: **07/129,834**

(22) Filed: **Dec. 8, 1987**

(51) **Int. Cl.**[7] **A61F 2/06**; A61F 11/00; A61B 19/00; A61B 17/00

(52) **U.S. Cl.** **623/1.46**; 623/1.11; 623/1.13; 623/1.39; 623/1.42; 606/151; 606/108; 606/195; 128/898

(58) **Field of Search** ..... 128/1 R, 334 C, 128/334 R, 898; 623/1, 12, 1.1–1.15, 1.18, 623/1.2–1.23, 1.44–1.46, 1.3, 1.36; 606/108, 606/151, 190–194, 198; 604/264, 265, 280

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,521,727 A	*	9/1950	Kappen	128/334 C
3,034,510 A		5/1962	Kittel	
3,044,497 A		7/1962	Rebut	
3,536,073 A		10/1970	Farb	128/214.4
3,588,920 A		6/1971	Wesolowski	
3,774,596 A		11/1973	Cook	128/5
3,823,720 A		7/1974	Tribble	128/350
3,937,224 A		2/1976	Uecker	128/348
4,122,858 A		10/1978	Schiff	128/348
4,130,904 A		12/1978	Whalen	3/1.4
4,140,126 A		2/1979	Chiudhury	128/325
4,389,208 A		6/1983	LeVeen et al.	604/95
4,398,910 A		8/1983	Blake et al.	604/93
4,406,656 A		9/1983	Hattler et al.	604/280
4,417,576 A		11/1983	Baran	128/207.15
4,577,637 A		3/1986	Mueller, Jr.	128/658
4,617,932 A		10/1986	Kornberg	128/334 R
4,647,416 A		3/1987	Seiler, Jr. et al.	264/118
4,739,762 A	*	4/1988	Palmaz	623/1
4,740,207 A	*	4/1988	Kreamer	623/12
5,199,939 A		4/1993	Dake et al.	600/3
5,213,561 A		5/1993	Weinstein et al.	600/7
5,354,257 A		10/1994	Roubin et al.	600/7
5,484,384 A		1/1996	Fearnot	600/3

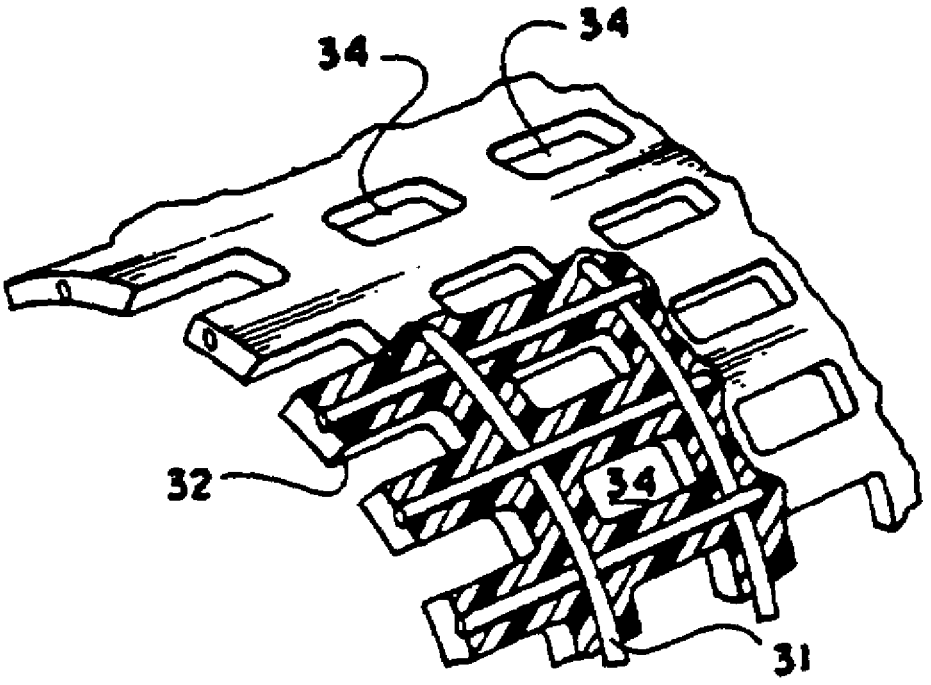
* cited by examiner

Primary Examiner—David J. Isabella
(74) *Attorney, Agent, or Firm*—Thomas, Kayden, Horstemeyer & Risley, LLP

(57) **ABSTRACT**

A prosthesis for use in preventing restenosis after angioplasty is formed of plastic or sheet metal, and is expandable and contractable for placement. The prosthesis can be inserted while in a collapsed position, then expanded and locked at the larger diameter. Spring force can be provided by the material itself, or metal springs can be embedded within the walls of the prosthesis. Preferably, the walls have holes therethrough to promote tissue growth; and, in one embodiment, the holes are in the form of slots so that the prosthesis is segmented and can bend longitudinally.

42 Claims, 2 Drawing Sheets



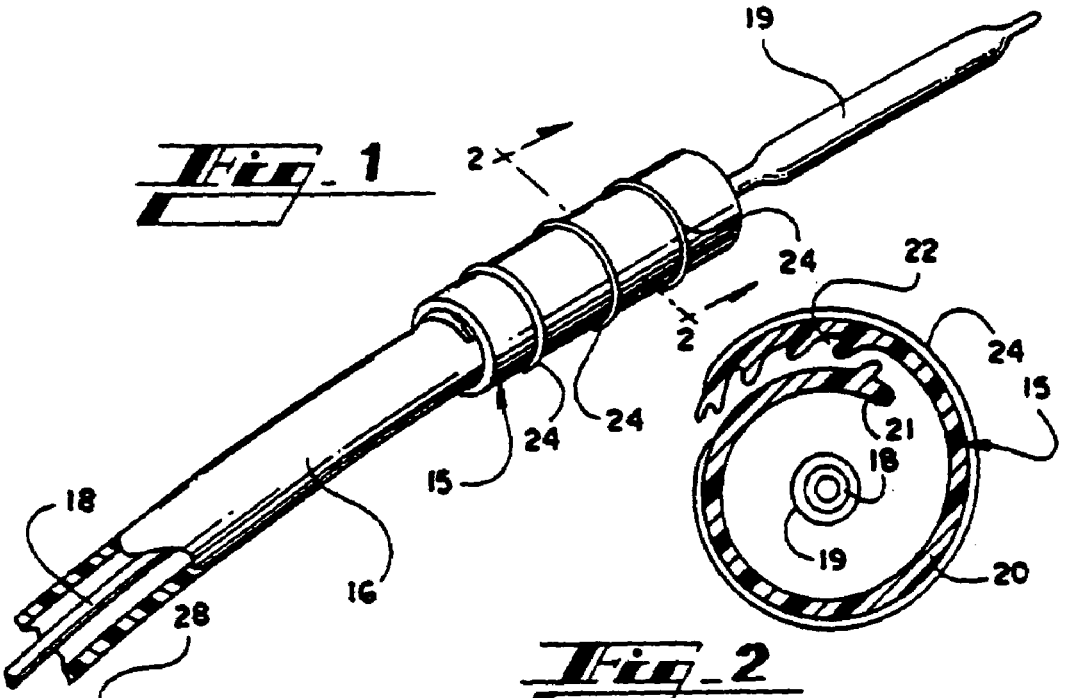
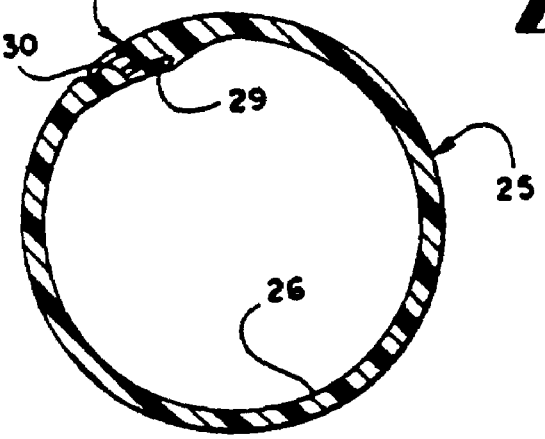


Fig_1

Fig_2



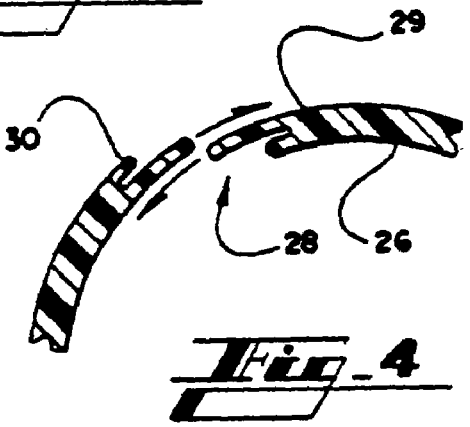


Fig_3

Fig_4

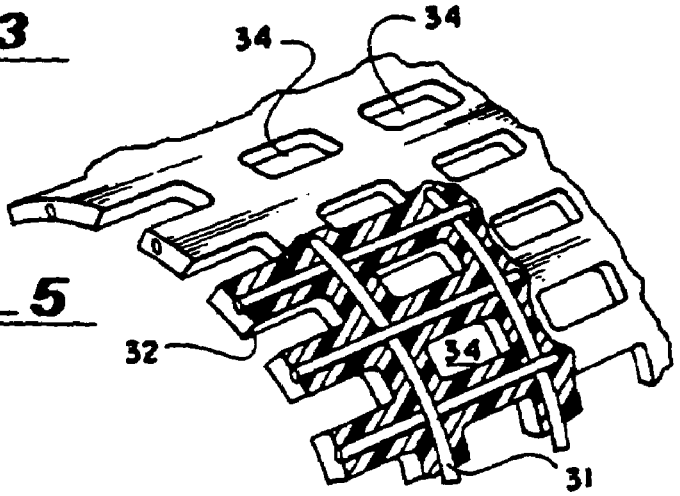


Fig_5

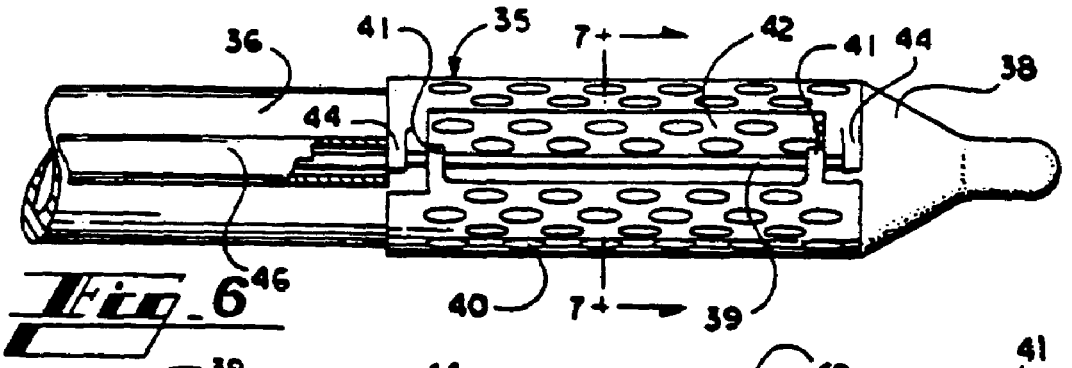


Fig_6

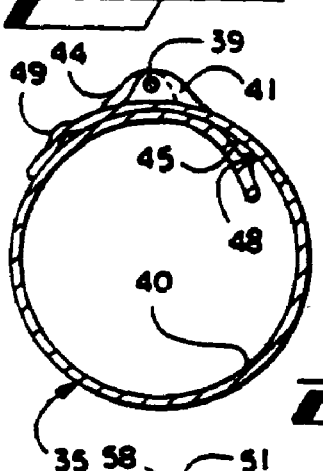


Fig_7

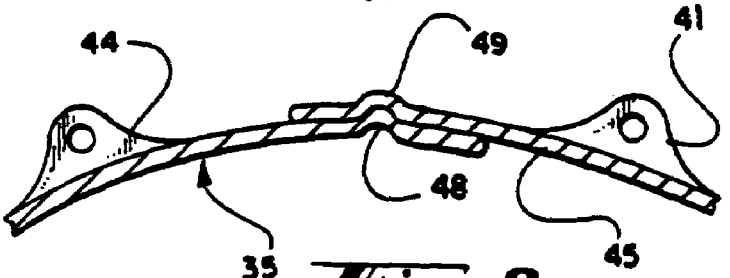


Fig_8

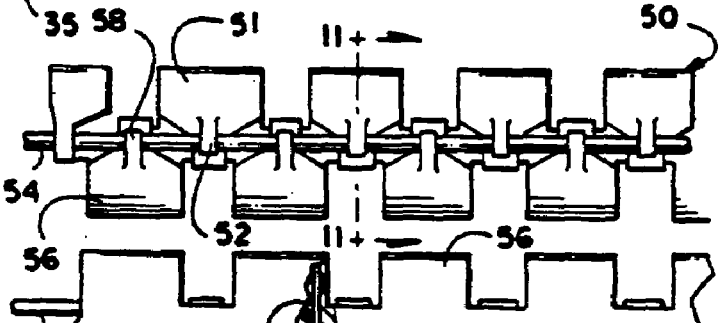


Fig_9

Fig_10

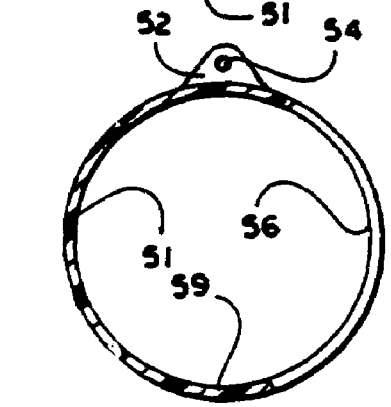


Fig_11

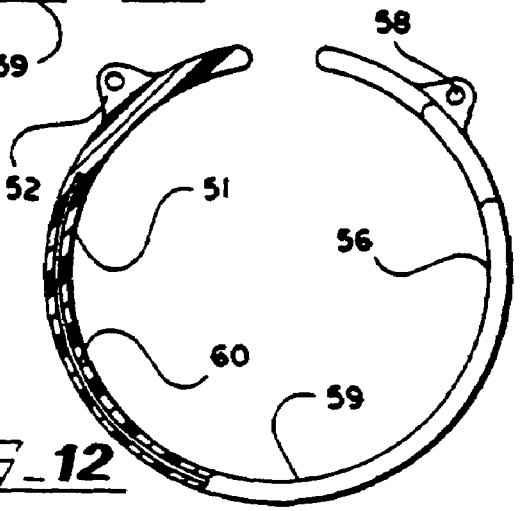


Fig_12

ANGIOPLASTY STENT

INFORMATION DISCLOSURE STATEMENT

There has been considerable use of balloon angioplasty due to stenosis in arteries having atherosclerotic plaque and the like in an effort to enlarge the lumen and to provide adequate blood flow. While such angioplasty has been successful, it has been found that in many cases re-stenosis requires that the procedure be repeated.

More recently, there have been efforts at following the balloon angioplasty with placement of a stent, the stent being in the nature of a sleeve that will mechanically maintain some minimum lumen diameter.

It will be obvious that, in order to place a stent utilizing the balloon angioplasty technology, the stent must necessarily have a sufficiently small external diameter to be moved into the desired area by some means such as a catheter, then to be expanded, both to be held in place by the arterial elasticity and to provide the minimum lumen diameter. Prior stents have generally taken the form of wire mesh that is collapsed for placement into the artery, then expanded, either by means of a balloon or by its own elasticity. The stent is generally held in place simply by the arterial elasticity in the first instance, and it has been found that epithelialization takes place throughout the stent so that the entire stent becomes effectively imbedded in the vessel wall.

The prior art stents, being woven stainless steel wire or the like tend not to be very flexible longitudinally so that their primary use is in straight portions of vessels. Also, inflation of the balloon is required to expand the wire mesh to its desired size in some cases, while other wire mesh stents tend to take a particular size, and must be held by a sleeve or the like during placement.

SUMMARY OF THE INVENTION

This invention relates generally to prostheses, and is more particularly concerned with a prosthesis in the form of a stent to be placed in a vessel for mechanically maintaining an opening.

This invention provides a stent for maintaining a minimum opening through an artery or the like, the stent being in the form of a sleeve having a discontinuity so the sleeve has a collapsed position to be assumed during placement of the stent, and an expanded position for use in its final location for maintaining the desired opening. In one embodiment of the invention, the stent may be carried by one catheter while a second coaxial catheter in the nature of a conventional balloon catheter is carried therein. This arrangement allows use of the balloon catheter to provide a mechanical opening in the vessel, then to allow the stent to be slipped into place over the balloon. The balloon can then be used to manipulate the stent for any necessary opening of the stent and disengagement of the stent from the coaxial catheter. It is also contemplated that the stent of the present invention can be carried by a single, generally conventional balloon catheter.

The stent of the present invention may selectively be biased towards a closed position and lockable in an open position, or biased in an open position and lockable in a closed position. In the former case, the stent will be put into place in its collapsed condition, then forcibly expanded by a balloon or the like to the desired locked condition. In the latter case, the stent may be held by a pin or the like in its collapsed condition, and the pin removed to allow the stent to assume its open position.

The stent of the present invention may be made from any of numerous materials, including metal or the like, and also including various plastic materials. The plastic materials may be simply homogeneous molded plastics, or may comprise a plastic covering over a knit or woven mesh. The knit or woven mesh may, in turn, be metal or plastic. The precise material can be selected to achieve the desired features of the stent.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will become apparent from consideration of the following specification when taken in conjunction with the accompanying drawings in which:

FIG. **1** is a perspective view showing one form of stent made in accordance with the present invention and carried by a coaxial catheter;

FIG. **2** is an enlarged cross-sectional view taken substantially along the line **2**—**2** in FIG. **1**;

FIG. **3** is a cross-sectional view of a slightly modified form of stent shown in its open and locked position;

FIG. **4** is a fragmentary view showing the stent of FIG. **3** after expansion beyond its maximum, open position;

FIG. **5** is a fragmentary perspective view, partially in cross-section, showing one form of material for use in constructing the stents of the present invention;

FIG. **6** is an elevational view showing another modified form of stent made in accordance with the present invention, the stent being carried on a catheter;

FIG. **7** is a cross-sectional view taken substantially along the line **7**—**7** in FIG. **6**;

FIG. **8** is a fragmentary view showing the stent of FIG. **7** after expansion;

FIG. **9** is a top plan view of another modified form of stent made in accordance with the present invention, the stent being shown without the carrying catheter;

FIG. **10** is a bottom plan view of the device shown in FIG. **9**;

FIG. **11** is an enlarged cross-sectional view taken substantially along the line **11**—**11** in FIG. **9**; and,

FIG. **12** is a view similar to FIG. **11** but showing the stent in its expanded condition.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Referring now more particularly to the drawings, and those embodiments of the invention here presented by way of illustration, FIG. **1** shows a stent generally indicated at **15**, the stent **15** being carried by a catheter **16**. The catheter **16** is one of two coaxial catheters, the other catheter **18** being a generally conventional balloon catheter having the balloon **19** at its distal end.

It will be understood by those skilled in the art that, in conventional balloon angioplasty, a catheter such as the catheter **18** is threaded through the arterial system to place the balloon at the location of the stenosis. The balloon **19** is then inflated to urge the arterial wall outwardly and open the lumen in the artery. This same technique will be utilized with the arrangement shown in FIG. **1** of the drawings, the balloon **19** acting to perform the angioplasty; however, after the vessel is sufficiently open by means of the balloon **19**, the coaxial catheter **16** will be manipulated to urge the stent **15** in place over the balloon **19**. After the stent **15** is over the balloon **19**, the balloon **19** will be inflated to urge the stent outwardly to its opened condition.

Referring to FIG. **2** of the drawings, it will be seen that the stent **15** includes a wall **20**, the wall **20** having sufficient memory that the stent as a whole tends to maintain its collapsed condition. One end of the wall **20** is provided with a hook **21** for engagement with one of a plurality of complementary hook means **22**. The hook **21** will necessarily be biased outwardly sufficiently that, as the hook **21** is urged past the plurality of hook means **22**, the hook **21** will engage each of the hooks **22**. Because of this arrangement, when the balloon **19** is not further inflated, the hook **21** will remain engaged with one of the hooks **22** to prevent collapse of the stent **15**.

It will also be noticed that the stent **15** contains a plurality of generally circumferential ribs **24**. It is contemplated that the ribs **24** will engage the arterial walls sufficiently to prevent inadvertent movement of the stent after placement and removal of the catheter **16**. As will be discussed hereinafter, the stent **15** may also contain a plurality of openings to allow tissue to grow therethrough and further hold the stent **15** in place.

Looking now at FIGS. **3** and **4** of the drawings, it will be seen that the stent **25** is a slightly modified form of the stent **15**. The stent **25** includes the wall **26** which will be biased towards collapse as is the wall **20** of the stent **15**. Once the stent **25** is urged to its expanded condition, the interlocking hook means **28** will become engaged as shown in FIG. **3** to prevent collapse of the stent **25** and maintain the stent in its maximum, open condition.

It will be understood that there may be times when the stent is improperly placed, or for other reasons must be removed. With the stent **25**, the ends **29** and **30** of the wall **26** are so biased that, when the stent **25** is expanded so far that the ends **29** and **30** are released from engagement, the end **29** will move inwardly and the end **30** will move outwardly. On subsequent release of the stent **25**, the walls **29** and **30** have exchanged places so that the hook means **28** cannot now engage. As a result, the stent **25** will collapse to its minimum external diameter.

Though many different materials may be utilized in forming the stents of the present invention, one form of material is illustrated in FIG. **5** of the drawings. In FIG. **5** there is a woven network indicated at **31**. This woven network may be metal such as stainless steel or the like, or may be a knit or woven plastic material such as polyester filaments. If the network **31** is made of metal, the intersections of the materials can be soldered or spot welded, and if the network is polyester or other thermoplastic, the intersections can be sonically welded or otherwise heat sealed to one another.

Following provision of the network **31**, the network **31** is covered by a plastic material indicated at **32**. The material **32** can again be any of numerous materials, so long as the material is implantable. Nevertheless, numerous plastic materials including polyethylene, polyester, polytetraflouroethylene and others can be utilized.

As illustrated in FIG. **5**, the network **31** is simply coated with the material **32** so that openings **34** are distributed throughout the material. While the openings **34** are not necessarily so uniformly distributed, it will be understood that the use of a plurality of openings **34** promotes epithelialization to promote incorporation of the stent into the vessel wall.

Turning now to FIG. **6** of the drawings, there is a stent indicated at **35** carried at the end of a catheter **36**. The catheter **36** includes a balloon **38** as is known in the art.

While the above described stents have been biased inwardly and have been forced outwardly, the stent **35** is biased outwardly and is forced inwardly and retained by means of a pin **39**. For a full understanding of the stent **35**, attention is directed to FIGS. **6**, **7** and **8** of the drawings which show both plan view and cross-sectional views of the stent **35**.

The stent **35** is here shown as having a generally smooth wall **40** having a plurality of openings **43** in accordance with the foregoing discussion. The wall **40** is biased outwardly towards its maximum diameter; however, for placement by means of the catheter **36**, the stent **35** is urged inwardly to its minimum diameter, and the stent is provided with a first pair of lugs **41** carried on the end **42** of the wall **40**, and second pair of lugs **44** carried generally towards the opposite end **45** of the wall **40**. When the wall **40** is urged inwardly to collapse the stent **35**, appropriate openings in the lugs **41** and **44** are aligned, and the pin **39** is placed therethrough to hold the stent **35** in its collapsed position.

As is shown in FIG. **6** of the drawings, it is contemplated that the pin **39** will be in the form of a wire that extends along the catheter **36**, contained within a channel **46**. With this arrangement, the pin **39** will extend to the lug **44** at the distal end of the stent **35**, and it will be understood that the distal end lug **44** may have a hole that does not extend completely through the lug in order to cover the end of the pin **39**. The pin **39** then extends the full length of the stent **35** and into the channel **46**. While not here illustrated, it will be understood that the pin **39** extends completely along the length of the catheter **36** so the pin **39** can be manipulated externally of the body so that, at the appropriate moment, the pin **39** can be removed from the lugs **41** and **44** and allow the stent **35** to expand.

As here shown, when the stent **35** expands, the ends **42** and **45** will remain overlapped to some extent. If desired, interlocking grooves **48** and **49** can be provided so the stent **35** has a relatively fixed expanded diameter.

Attention is next directed to FIGS. **9–12** of the drawings which show another modified form of stent. The stent **50** is similar to the stent **35** in that it is biased outwardly and is forcibly held inward by a pin; however, the stent **50** is considerably different from the stent **35** in that the stent **50** is of a somewhat segmented construction to allow longitudinal flexibility.

In the top plan view shown in FIG. **9** of the drawings, it will be seen that the stent **50** includes a plurality of segments **51**, each segment **51** having a lug **52** thereon for receipt of a pin **54**. The segments **51** are interspersed with segments **56** on the opposite side of the pin **54**, the segments **56** having lugs **58** thereon. As is better shown in FIG. **10** of the drawings, there is a generally continuous spine **59** extending along the bottom of the stent **50** and interconnecting all of the segments **51** and **56**. Because of this construction, it will be seen that the stent **50** will be readily bendable along its longitudinal axis, the bending being resisted only by the relatively narrow spine **59**. Furthermore, it will be understood that the individual segments **51** and **56** can be made much shorter to provide for tighter radii, or relatively long in the event the stent is not intended to be very flexible.

Though the stent **50** in FIGS. **9–12** of the drawings is not shown in conjunction with a catheter, it will be understood by those skilled in the art that the stent will be put into place using an arrangement such as that shown in FIG. **6** of the drawings. The catheter **36** and wire channel **46** would be the same, the specific stent being the only difference.

FIG. **11** of the drawings shows the cross-sectional shape of the stent **50** while the stent is held in its closed, or collapsed, condition by the pin **54**. When the pin **54** is removed, the stent **50** will expand to the condition shown in FIG. **12** of the drawings. It will of course be recognized that a balloon, such as the balloon **38**, may be utilized to assist in urging the walls of the stent outwardly to the desired position.

The material from which the stent **50** is made may be any of the numerous materials previously mentioned, including the material shown in FIG. **5** of the drawings. Because the stent **50** is made up of a plurality of individual segments **51** and **56**, there is no particular need for additional openings in the wall of the stent, the spaces between the segments providing adequate openings for initial fluid drainage and subsequent epithelialization.

Simply by way of example, FIGS. **10** and **12** illustrate the inclusion of a filament **60** in the wall of the stent. The purpose of the filament **60** is to show that the stent **50** can be made of a plastic material having sufficient memory to be urged to the open condition as shown in FIG. **12**; or, the stent **50** can be made of a relatively flaccid fabric or the like having spring filaments **60** imbedded therein for urging the stent **50** to its open position. Also, the stent **50** can be made entirely of metal, including well known alloys of platinum and gold, or chromium and cobalt.

From the foregoing discussion it will be understood that the present invention provides an arterial stent and a method for placing the stent for preventing restenosis following angioplasty or other mechanical opening of the lumen in an artery. While several specific designs and materials have been disclosed, those skilled in the art will recognize that the materials must be implantable, and all portions of the stent must be sufficiently smooth to prevent trauma during placement. Further, all corners and the like should be well rounded to promote epithelialization without subsequent trauma due to the presence of sharp edges during natural body motions.

It will of course be understood by those skilled in the art that the particular embodiments of the invention here presented are by way of illustration only, and are meant to be in no way restrictive; therefore, numerous changes and modifications may be made, and the full use of equivalents resorted to, without departing from the spirit or scope of the invention as outlined in the appended claims.

What is claimed is:

1. A prosthesis for use in maintaining an opening within a vessel, said prosthesis comprising a sleeve having a wall, said wall defining a discontinuity longitudinally thereof providing a first edge and a second edge of said wall, said first edge being selectively receivable within said sleeve for allowing said sleeve selectively to assume a first position wherein said first edge of said wall moves inwardly for providing a collapsed diameter of said sleeve, and a second position wherein said wall moves outwardly for providing an expanded diameter of said sleeve, means for urging said wall in one direction towards either said collapsed diameter or said expanded diameter, and locking means for preventing motion of said wall by said means for urging said wall in one direction,

said means for urging said wall in one direction including memory of said wall,

said one direction being inwardly towards said collapsed diameter, said locking means comprising a first hook means carried by said first edge of said wall, and a second hook means carried by said second edge of said wall, said first and second hook means being engageable with each other for fixing the diameter of said sleeve.

2. A prosthesis as claimed in claim **1**, said first edge and said second edge of said wall being normally overlapped at said discontinuity, said first and second hook means being carried by said wall adjacent to said discontinuity, said wall adjacent to said discontinuity being biased so that said first hook means and said second hook means interchange with each other when said wall is no longer overlapped, the arrangement being such that said first and second hook means normally engage for fixing the diameter of said sleeve, and said first and second hook means cannot engage when said hook means interchange with each other.

3. A prosthesis as claimed in claim **1**, said one direction being outwardly towards said expanded diameter, said locking means including a plurality of lugs, at least one lug of said plurality of lugs being on each side of said discontinuity in said wall, and pin means receivable through said lugs for holding said sleeve inwardly at said collapsed diameter.

4. A prosthesis as claimed in claim **3**, said lugs being so placed that said wall is overlapped when said lugs are aligned, said pin comprising a wire extending longitudinally of said sleeve and selectively movable for disengagement from said lugs.

5. A prosthesis as claimed in claim **4**, and further including second locking means for fixing the diameter of said wall at said expanded diameter.

6. A prosthesis as claimed in claim **1**, said wall comprising a plurality of segments, said sleeve having a top and a bottom extending longitudinally of said sleeve, a spine extending longitudinally of said sleeve along said bottom of said sleeve, each segment of said plurality of segments extending from said spine, around one side of said sleeve and to said top of said sleeve, said plurality of segments being spaced apart along each side of said spine so that said sleeve is longitudinally bendable.

7. A prosthesis for use in maintaining an opening within a vessel, said prosthesis comprising a sleeve having a wall, said wall defining a discontinuity longitudinally thereof for providing a first edge and a second edge of said wall, said first edge being selectively receivable within said sleeve for allowing said sleeve selectively to assume a first position wherein said first edge of said wall moves inwardly for providing a collapsed diameter of said sleeve, and a second position wherein said wall moves outwardly for providing an expanded diameter of said sleeve, means for urging said wall in one direction towards either said collapsed diameter or said expanded diameter, and locking means for preventing motion of said wall by said means for urging said wall in one direction, said wall comprising a plurality of segments, said sleeve having a top and a bottom extending longitudinally of said sleeve, a spine extending longitudinally of said sleeve along said bottom of said sleeve, each segment of said plurality of segments extending from said spine, around one side of said sleeve and to said top of said sleeve, said plurality of segments being spaced apart along each side of said spine so that said sleeve is longitudinally bendable and further including a plurality of lugs, each lug of said plurality of lugs being carried generally on one of said segments at said top of said sleeve, the arrangement being such that said sleeve is moved inwardly to said collapsed diameter when said lugs are aligned, and a pin receivable through said lugs constituting said locking means.

8. A prosthesis as claimed in claim **7**, said means for urging said wall in one direction including memory of said wall.

9. A prosthesis as claimed in claim **7**, said means for urging said wall in one direction including spring means embedded within said wall.

10. A stent for placement within a vessel, said stent being generally cylindrical in shape and having a wall, said wall defining a discontinuity longitudinally thereof for providing a first edge and a second edge of said wall, said first edge being selectively receivable within said sleeve for allowing said sleeve selectively to assume a first position wherein said

wall moves inwardly for providing a collapsed diameter of said sleeve, and a second position wherein said wall moves outwardly for providing an expanded diameter of said sleeve, means for urging said wall in one direction towards either said collapsed diameter or said expanded diameter, said wall being formed of sheet material defining a plurality of openings therethrough.

11. A stent as claimed in claim **10**, said sheet material comprising an implantable metal.

12. A stent as claimed in claim **10**, said sheet material comprising an implantable plastic material formed into said sheet material.

13. A stent as claimed in claim **12**, said sheet material further including a filamentary mesh coated with said plastic material.

14. A stent as claimed in claim **12**, said sheet material further including a plurality of spring members embedded within said sleeve.

15. A method of placement of a sleeve into an affected lumen of a human body following angioplasty for preventing re-stenosis of the affected lumen and maintaining at least a minimum opening in the lumen comprising:

providing a radially collapsible sleeve formed in a mesh, a coating of material applied to said mesh and defining a plurality of openings throughout the mesh to allow tissue to grow there through, and said mesh biased toward its collapsed position,

providing a catheter,

mounting the sleeve in its radially collapsed position on the catheter,

inserting the catheter with the collapsed sleeve mounted thereon into a lumen of the body,

carrying the sleeve in its collapsed position with the catheter along the length of the lumen to a position in the lumen where the minimum opening in the lumen is to be established,

radially expanding the catheter inside the sleeve,

radially expanding the sleeve in response to the radial expansion of the catheter in the position of the lumen where the minimum opening in the lumen is to be established,

radially expanding the lumen in response to the radial expansion of the sleeve,

maintaining the sleeve in its radially expanded position,

collapsing the catheter inside the sleeve,

withdrawing the catheter from the sleeve and from the lumen,

promoting epithelialization of the lumen about the sleeve and its openings for incorporating the sleeve into the lumen, and

preventing re-stenosis of the lumen with the sleeve.

16. The method of claim **15**, wherein the step of providing a catheter comprises providing a catheter with a balloon at its distal end, and the step of radially expanding the catheter comprises inflating the balloon.

17. The method of claim **15**, wherein the sleeve when in its collapsed position defines a longitudinal gap and the sleeve is in the form of a coil, and wherein the step of radially expanding the sleeve comprises transforming the sleeve from its coiled position into an open cylindrical position.

18. The method of claim **17**, wherein the step of radially expanding the sleeve comprises expanding the sleeve to a predetermined circumference.

19. The method of claim **17**, wherein the sleeve has ends adjacent its gap, and the step of maintaining the sleeve in its radially expanded position comprises locking the ends of the sleeve together.

20. The method of claim **19**, wherein the step of locking the ends of the sleeve together comprises placing the ends of the sleeve in overlying relationship, and locking the ends of the sleeve together in overlying relationship.

21. The method of claim **19**, wherein the sleeve has connectors on at least one of its ends, and wherein the step of locking the ends of the sleeve together comprises locking the connectors to the ends to establish the sleeve in a position of a predetermined circumference.

22. A method of placement of a sleeve into an affected lumen of a human body for preventing re-stenosis following angioplasty of the affected lumen and maintaining at least a minimum opening in the lumen, comprising:

providing a radially collapsible sleeve biased toward its radially collapsed position and formed in a mesh, a coating applied to the mesh defining a plurality of openings throughout the mesh that allow tissue to grow through the openings and forming a smooth surface-on the mesh, with said sleeve positioned in its radially collapsed position,

carrying the sleeve in its collapsed position with a catheter along the length of a lumen to a position in the lumen where the minimum opening in the lumen is to be established,

radially expanding the sleeve,

radially expanding the lumen in response to the expansion of the sleeve, and locking the sleeve in its radially expanded position, to promote epithelialization through the openings of the sleeve to promote incorporation of the stent into the vessel wall.

23. The method of claim **22**, wherein the step of locking the sleeve in its radially expanded position comprises locking the sleeve to itself in response to radially expanding the sleeve.

24. The method of claim **22**, wherein the step of providing a sleeve formed in a mesh and a coating applied to the mesh, includes the coating defining rounded surfaces for avoiding trauma to the lumen.

25. A method of placement of a sleeve into an affected lumen of a human body for preventing re-stenosis following angioplasty of the affected lumen and maintaining at least a minimum opening in the lumen, comprising:

providing a radially collapsible sleeve formed in a mesh defining a plurality of openings through out the mesh that allow tissue to grow through the openings and a coating applied to the mesh for defining a plurality of openings that allow promotion of epithelialization, with said sleeve positioned in its radially collapsed position,

carrying the sleeve in its collapsed position along the length of a lumen to a position in the lumen where the minimum opening in the lumen is to be established,

radially expanding the sleeve,

radially expanding the lumen in response to the expansion of the sleeve, and locking the sleeve in its radially expanded position, to promote epithelialization through the openings of the sleeve to promote incorporation of the stent into the vessel wall,

wherein the step of providing a sleeve comprises providing a sleeve that defines a longitudinal gap with said sleeve formed in a coil and with first and second ends adjacent the gap, and a hook means on the first end facing the second end, and first and second hook means on the second end facing the first end, and

wherein the step of locking the sleeve comprises engaging the hook means of said first end with the first hook means of the second end to expand the sleeve to a first diameter, and engaging the hook means of the first end with the second hook means of the second end to expand the sleeve to a second diameter.

26. The method of claim **25**, and further including the step of opening the sleeve by expanding the sleeve so that its ends move beyond each other and collapsing the sleeve with the hook means of each sleeve end facing away from the opposite sleeve end.

27. The method of claim **22**, and further including the step of retarding movement of the sleeve along the length of the lumen in response to expanding the sleeve.

28. A method of placement of a sleeve into an affected lumen of a human body for preventing re-stenosis following angioplasty of the affected lumen and maintaining at least a minimum opening in the lumen, comprising:

providing a radially collapsible sleeve formed in a mesh defining a plurality of openings that allow tissue to grow through the openings and a coating applied to the mesh for defining a plurality of openings that allow promotion of epithelialization, with said sleeve radially collapsed,

carrying the radially collapsed sleeve along the length of a lumen to a position in the lumen where the minimum opening in the lumen is to be established,

radially expanding the sleeve,

radially expanding the lumen in response to the expansion of the sleeve, and locking the sleeve in its radially expanded position, to promote epithelialization through the openings of the sleeve to promote incorporation of the stent into the vessel wall,

wherein the step of providing a radially collapsible sleeve comprises providing a sleeve having circumferential ribs protruding from the sleeve intermediate the ends of the sleeve, and the step of expanding the sleeve comprises expanding the protruding circumferential ribs into contact with the lumen, and retarding movement of the sleeve along the length of the lumen with engagement of the ribs with the lumen.

29. The method of claim **28**, wherein the step of providing a radially collapsible sleeve formed in a mesh comprises providing a sleeve with a woven network with intersections connected together.

30. A method of placement of a sleeve into an affected lumen of a human body following angioplasty for preventing re-stenosis of the affected lumen and maintaining at least a minimum opening in the lumen comprising:

providing a sleeve formed in a mesh and a coating applied to said mesh and defining a plurality of openings throughout the mesh to allow tissue to grow there through,

providing a catheter,

mounting the sleeve in a radially collapsed position on the catheter,

inserting the catheter with the collapsed sleeve mounted thereon into a lumen of the body,

carrying the sleeve in its collapsed position with the catheter along the length of the lumen to a position in the lumen where the minimum opening in the lumen is to be maintained,

radially expanding the sleeve in the position of the lumen where the minimum opening in the lumen is to be maintained,

radially expanding the lumen in response to the radial expansion of the sleeve,

withdrawing the catheter from the sleeve and from the lumen,

promoting epithelialization of the lumen about the sleeve and its openings for incorporating the sleeve into the lumen, and

retarding re-stenosis of the lumen with the sleeve.

31. The method of claim **30**, wherein the step of radially expanding the sleeve comprises expanding the sleeve to a predetermined circumference.

32. The method of claim **30**, wherein the step of providing a sleeve comprises providing sleeve having circumferential ribs protruding from the sleeve intermediate the ends of the sleeve, and the step of expanding the sleeve comprises expanding the protruding circumferential ribs into contact with the lumen, and retarding movement of the sleeve along the length of the lumen with engagement of the ribs with the lumen.

33. The method of claim **30**, wherein the step of providing a sleeve formed in a mesh and a coating applied to said mesh and defining a plurality of openings throughout the mesh to allow tissue to grow there through, includes the coating defining a plurality of openings and rounded surfaces for avoiding trauma to the lumen.

34. A stent for placement into a lumen of the human body and for maintaining an opening within the lumen, said stent comprising:

a radially collapsible sleeve formed in a mesh,

a coating of material applied to the mesh and defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, and

said mesh being biased toward its collapsed position.

35. A stent as claimed in claim **34** wherein said mesh being biased toward its collapsed position comprises the memory of said sleeve.

36. A stent as claimed in claim **34** and further including locking means for fixing an expanded diameter of said sleeve.

37. A stent as claimed in claim **34** wherein said mesh being biased toward its collapsed position includes spring means embedded within said sleeve.

38. A stent as claimed in claim **34** wherein when said sleeve is in its collapsed position it is in the form of a coil, and when the sleeve is expanded it is in the form of a cylinder.

39. A stent for placement into a narrowed opening of a lumen of the human body and for maintaining at least a minimum opening within the lumen, said stent comprising:

a radially collapsible sleeve formed in a mesh and a coating applied thereto,

said sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, and

said mesh being biased toward either its collapsed position or its expanded position.

40. A stent as claimed in claim **39**, and further including a plurality of generally circumferential ribs protruding from said sleeve for engagement with the lumen and limiting movement of the sleeve in the lumen.

41. A stent as claimed in claim **39** wherein when said sleeve is in its expanded position it is in the form of a cylinder.

42. A stent as claimed in claim **39**, wherein said mesh is a woven network with intersections connected together, and said coating is applied to said woven network.

* * * * *

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC.

(b) County Of Residence Of First Listed Plaintiff: New Castle
(Except In U.S. Plaintiff Cases)

DEFENDANT

WALL CARDIOVASCULAR TECHNOLOGIES, LLC

County Of Residence Of First Listed Defendant:
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) Attorneys (Firm Name, Address, And Telephone Number)
Josy W. Ingersoll, Esquire
John W. Shaw, Esquire
Adam W. Poff, Esquire
Andrew A. Lundgren, Esquire
Young Conaway Stargatt & Taylor, LLP
1000 West Street, 17th Floor
Wilmington, DE 19801
(302) 571-6600

Attorneys (If Known)

II. BASIS OF JURISDICTION (PLACE AN X IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place An X In One Box For Plaintiff And One Box For Defendant) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	¤ 1	¤ 1	Incorporated or Principal Place of Business in This State	¤ 4	¤ 4
Citizen of Another State	¤ 2	¤ 2	Incorporated and Principal Place of Business in This State	¤ 5	¤ 5
Citizen or Subject of a Foreign Country	¤ 3	¤ 3	Foreign Nation	¤ 6	¤ 6

V. NATURE OF SUIT (Place An X In One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence Habeas Corpus
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 U.S.C. 881
- ☐ 630 Liquor Laws
- ☐ 640 R R & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl Ret Inc Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 U.S.C. 158
- ☐ 423 Withdrawal 28 U.S.C. 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 U.S.C. 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates, etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 U.S.C. 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

IV. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding ☐ 2 Removed from Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.):
35 U.S.C. § 1 et seq.

Brief description of cause:
Action for declaratory judgment of noninfringement, invalidity, and unenforceability.

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A UNDER F.R.C.P. 23 **CLASS ACTION** ☐ YES ☒ NO **DEMAND $**

Check YES only if demanded in complaint
JURY DEMAND: ☐ YES ☒ NO

VIII. RELATED CASE(S) (See instructions)
IF ANY JUDGE: Hon. Sue L. Robinson DOCKET NUMBER: C.A. Nos. 07-333-SLR; 07-348-SLR; 07-409-SLR; 07-765-SLR (D. Del.)

DATE August 6, 2008 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No. 08-489

ACKNOWLEDGMENT OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 2 COPIES OF AO FORM 85.

8/6/08
(Date forms issued)

X
(Signature of Party or their Representative)

X
(Printed name of Party or their Representative)
MAURA C. McGEHON

Note: Completed receipt will be filed in the Civil Action